TCVP STEPS

Next 3 weeks

Get final (oral) decision, with all necessary management buy-in, on path forward (denial; denial with changes to registration; cancellation)

Most of the work in this phase is up to OPP – they need to make a proposed decision, and vet it with whatever management will be involved. Scientists and risk managers need to accept that they need to make decision with existing science (no more data; not much time to work out any remaining science issues). Top managers will have to be available to make final decision in relatively short time. OGC will have to be available to provide guidance as needed. Broad rationale for decision needs to be resolved in this time period as well (details can be fleshed out later). Initial steps include:

- Get Rick to agree to deadline for making the decision - immediate
- Discuss deadline with Alex - immediate
- Alert PRD staff to deadline – immediate
- Inform Hartz of realities of situation (particularly that we will be making decision in short order, without the ability to consider any new information) – (this is an optional step that should be considered, and the timing of this notification should be considered as well)
- Consider whether you want to give a heads-up to one of the lawyers in the ALJ's office. I recommend doing so, but it's not required. Heads-up here would alert them to the court's "expectation" of expedition if we end up seeking cancellation – they may have some insight as to whether timing should be addressed in the NOIC. Might want to do this in writing for your protection – but whether done orally or in writing, make sure to not say anything about the merits of any potential cancellation.

If choice is denial (registration as currently formulated meets standard)

This is the simplest path conceptually. Written and signed denial needed by [whatever date is 90 days after court decision]. Only steps are sequential:

- Draft response
- Get management approval

If choice is denial with changes to registration required

This path presents Hartz with a choice that they will have to make quickly. IF we determine that the existing registration doesn't meet the standard, but that an ***amended*** registration ***would*** meet the standard, our 90-response to the court will be determined by Hartz. If they do not agree to make the changes, we have to go the cancellation route (and we can determine whether or not to

identify modified terms as an alternative to cancellation). If Hartz submits a timely application for amended registration to modify the registration in a manner that enables us to deny the petition, we deny the petition. Note: the specific necessary modifications to registration must be identified in the next three weeks (or whenever the direction-determining decision needs to be made). Steps here include:

- Have early discussions with Hartz to try and get them to make a quick decision. This is critically important here.
- If a quick, satisfactory amendment comes in – grant the amendment and draft a denial (relying on the amended registration).
- If Hartz announces they will not amend, move to the cancellation path.
- If Hartz wants to negotiate something else – regroup and figure out next steps. This is where things will get complicated, and there will need to be discussions with management as to whether they will negotiate (in which case, there will need to be two concurrent efforts – one looking at negotiating, the other developing the cancellation papers) or whether we present Hartz with a "take it or leave it" offer (agree to our proposal or go to a cancellation hearing). If two concurrent efforts, consider having two separate leads in OGC, with one focusing on negotiations and the other drafting cancellation papers (I don't think you can wait very long before starting to prepare a draft NOIC if Hartz doesn't submit an amendment very quickly).

Cancellation Path

If the determination is to cancel (or we've identified alternative terms of registration that Hartz is unwilling to adopt), there are a number of steps that have to be taken. In the immediate term, those steps include:

- Talk to Hartz. If they're willing to voluntarily cancel, we generally have more flexibility the earlier a cancellation request is received. If they are willing to cancel, we'd need to figure out whether we'd allow a phase-out and if so, how long a phase-out we'd tolerate; what to do with existing stocks at all three levels (in registrants hands, other sale and distribution, use); and if we'd wish to have any modifications to terms of sale or use while sale or use is still allowed. Remind Hartz that subpart D kicks in if a notice of intent is issued. If Hartz submits a 6(f) request, I would think all we would need to do is let the court know that we're processing (and intend to act on) the request, the granting of which would moot out the petition.
- Figure out what steps we need to accomplish before getting back to the court. Is it enough to have made a decision and have publicly announced it? Must we have a draft NOIC ready to show the court (we generally do not make draft NOICs public unless and until the SAP meeting has been scheduled – if the SAP waives review, we would only make a final NOIC available).

For the cancellation itself, the following steps need to be taken:

- Form a cancellation team. This will help with the drafting of the NOIC, and will be necessary for any hearing.
- Remember to prepare something to alert the GC and Administrator to potential *ex parte* issues – it's good practice to move before necessary in this area. Scott should be able to help with what was done in this regard in the rodenticide case.
- Draft an NOIC. Generally, we like to identify witnesses and talk to them before drafting the notice – that probably won't be possible here, but it will add potential risks/complications for the process.
- If talks with registrants are going to occur during the time you're preparing a draft NOIC, consider having a separate "negotiation" team. That step's not necessary if the draft NOIC is not under time constraints, but it's probably appropriate under the circumstances for TCVP.
- Substantively, NOIC will have to identify the risks and benefits relevant to the action we're proposing to take, and the conclusory rationale for the action. Don't know what efforts program has made on the "benefits" side, but that side cannot be ignored. We'll also need to figure out how broad or narrow the cancellation rationale will be. For example, you could cancel solely looking at the pet care use and determining that the risks to children outweigh the benefits of the use. But if retention of the pet-care uses would eventually require cancellation of all the food uses of TCVP (because pet-care exposures would add too much to the "aggregate" risk cup such that the food uses no longer meet the "reasonable certainty of no harm" standard in section 408 and the tolerances would have to be revoked), that would impact the risk-benefit balance for the pet-care uses (harm side would now include loss of food use registrations as well as risks to kids).

- Once the strategy for the NOIC is clear, we should start drafting it. Historically, OGC has drafted NOIC's with close cooperation from OPP. As the NOIC is drafted, it's a good idea to identify the actual witness(es) that you'd want to employ in a hearing to make the substantive pointes made in the notice. That includes a witness to explain the ultimate risk-benefit determination (this should be some high-level manager in OPP or OCSPP). Remember that the hearing will focus on a hearing-requestor's objections to our notice – which makes it more difficult and cumbersome for us to add issues after the final NOIC is issued. So you can't really skimp on a draft NOIC without paying for it later.
- Once you have a draft NOIC, it must go for review to the SAP and USDA before it can be published.
- SAP meeting – this one takes some time. You can do a little advance work by alerting the SAP and asking them to set a date for a public-meeting with them (getting on the SAP's calendar typically requires some lead time). You can ask them for a waiver, but I'd recommend against doing so unless we really think that the SAP has previously looked at the science issue(s) involved in the cancellation and additional SAP review would be redundant. SAP is a FACA meeting – they typically hold a public meeting to address cancellation science. We typically give them a draft NOIC which is part of their public record for their public meeting. SAP proceedings are a little slower than the statute envisions. FIFRA

provides that we can ignore SAP if they don't comment within 30 days. The SAP likes to have the public documents available for public review for 30 days before their meeting; and they can get EPA comments within 30 days of the meeting, but that's a quick turn-around for them and they may ask for a little more time. Also, although we're not obligated to provide "charge" questions to the SAP, it's generally a good idea – asking them the right questions focuses their review on the issues we'd like them to look at. I think you need to send them the charge questions when you send them the draft NOIC – so folks will need to start work on them while the draft NOIC is nearing completion. Our scientists generally make a presentation before the SAP or sit on a panel to answer SAP's questions – you'll want to make sure their answers are consistent with the case you're trying to build. Finally, you have to address SAP comments in the final NOIC – that may delay the final NOIC a little (depending on the nature of the comments). OPP is in charge of the SAP step, but probably worth nudging them to make sure SAP review doesn't significantly delay things.

- USDA is conceptually easier – you can send them the draft NOIC at any time, and they have to get back to us in 30 days. USDA review is predominantly for them to comment on the impact of the cancellation on the agricultural economy – that won't be an issue here. Accordingly, it might be appropriate to ask USDA to waive their right to review. This is certainly a theoretical possibility – but insofar as TCVP involves an organo-phosphate and OPs are both at risk and often used agriculturally, USDA may well decline to waive review. Still worth talking with Rick about whether he'd like to request a waiver. OPP is in charge of this step.
- To issue a final NOIC, you need to address the comments (if any) by SAP and USDA. But keep in mind that the NOIC establishes the scope and boundaries of the hearing and serves the partial function of being EPA's opening statement – make sure every important issue you want to raise in the hearing is appropriately addressed in the NOIC (subject to time constraints) and that you're not saying stuff in the NOIC that you're going to walk away from at the hearing.
- Consider how you want to address "timing" issues (the court's expectation on the pace of the proceeding) in the NOIC. I think to keep faith with the court we'll have to say something.
- Once a hearing is requested and an ALJ appointed, pace of the proceeding is out of OPP's hands. But it's still (to some extent) in the Administrator's hands – you'll need to figure out how to deal with this paradigm. And you'll need to do so without stepping over any *ex parte* lines. Otherwise, you follow the lead of the ALJ.